

Attorney Docket No.: 9537-3
Application Serial No.: 10/658,932
Filed: September 9, 2003
Page 2 of 13

This listing of the claims replaces all prior versions in the application.

Listing of Claims:

1. (Previously Presented) An implantable prosthesis of shape generally similar to that of a spinal intervertebral disc, comprised of a biocompatible elastomer with a compressive modulus of elasticity less than about 100 megaPascals, with an ultimate strength in tension generally greater than about 100 kiloPascals, that exhibits the flexibility to allow at least 2 degrees of rotation between the top and bottom faces with torsions of at least about 0.01 N-m without failing.
2. (Previously Presented) A prosthesis according to Claim 1 wherein the device has an ultimate compressive strength sufficient to withstand a compressive load greater than 1 MegaPascals.
3. (Previously Presented) A prosthesis according to Claim 1 wherein the material used for the device has an ultimate strength in tension greater than about 5 MPa.
4. (Original) A prosthesis according to Claim 1 wherein the device is made of a single solid elastomeric material.
5. (Currently Amended) A prosthesis according to Claim 1 wherein the elastomer has a compressive modulus of elasticity of at least about ~~greater than~~ 1.0 MPa.
6. (Previously Presented) A prosthesis according to Claim 1 wherein the elastomer has a compressive modulus of elasticity less than 20 MPa.
7. (Previously Presented) A prosthesis according to Claim 1 wherein the device has a compressive modulus of elasticity less than about 10 MPa and greater than about 200 KPa.

Attorney Docket No.: 9537-3
Application Serial No.: 10/658,932
Filed: September 9, 2003
Page 3 of 13

8. (Previously Presented) A prosthesis according to Claim 1 wherein the elastomer has a compressive modulus of elasticity that is not constant.

9. (Original) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can expand at least 5% in at least one dimension over one day, in saline.

10. (Original) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can expand at least 50% in at least one dimension in vivo without injection of material.

11. (Previously Presented) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can expand at least 20% over one day in at least one dimension in vivo and can generate a cranial-caudal force of greater than about 1 Newton.

12. (Original) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can expand at least 100% by a combination of springs and elastomeric components.

13. (Previously Presented) A prosthesis according to Claim 1 the elastomer defines an exposed surface that is modified to provide specific surface characteristics.

14. (Original) A prosthesis according to Claim 13 wherein the surface characteristics are physically or biochemically modified to provide enhanced adhesion to a vertebral body.

15. (Previously Presented) A prosthesis according to Claim 13 wherein the surface includes a fabric.

Attorney Docket No.: 9537-3
Application Serial No.: 10/658,932
Filed: September 9, 2003
Page 4 of 13

16. (Previously Presented) A prosthesis according to Claim 13 wherein the surface includes a metal solid or mesh.

17. (Previously Presented) A prosthesis according to Claim 13 wherein the surface includes a porous structure with undercuts.

18. (Previously Presented) A prosthesis according to Claim 13 wherein the surface includes a rough surface greater than 5 nanometers.

19. (Previously Presented) A prosthesis according to Claim 13 wherein the surface includes a bioactive molecule.

20. (Previously Presented) A prosthesis according to Claim 1 wherein the surface characteristics of the prosthesis allow cellular ingrowth.

21. (Previously Presented) A prosthesis according to Claim 1 wherein surface characteristics of the elastomer are biochemically modified to provide enhanced water transport.

22. (Previously Presented) A prosthesis according to Claim 1 wherein surface characteristics of the prosthesis are physically modified to provide enhanced chemical transport.

23. (Previously Presented) A prosthesis according to Claim 1 wherein the device is a unitary non-articulating plateless body made of a single solid elastomer with a compressive modulus of elasticity between about 0.2 and 10 megaPascals with tab extensions for fixation to the adjacent vertebral bodies.

Attorney Docket No.: 9537-3
Application Serial No.: 10/658,932
Filed: September 9, 2003
Page 5 of 13

24. (Original) A prosthesis according to Claim 1 wherein the disc is composed of a material that contains a ring of continuous fiber.

25. (Previously Presented) A prosthesis according to Claim 1 that contains appendages to allow for physical attachment to the vertebral body and to prevent dislodgement in situ.

26. (Original) A prosthesis according to Claim 1 wherein the material is a cryogel.

27. (Original) A prosthesis according to Claim 1 wherein the material is a composite material composed of more than one substance.

28. (Original) A prosthesis according to Claim 1 that is a permanent implantable medical device.

29. (Currently Amended) A sterile prosthesis according to Claim 1 wherein the body is manufactured as an oval or kidney shape for use as a spinal disc prosthesis that substantially corresponds to a shape of a human spinal disc, ~~expands at least about 20% in height when placed in Normal saline solutions~~, has exposed fibers on the cranial and caudal surfaces, has a unitary non-articulating solid body, with the biocompatible elastomer having a compressive modulus of elasticity between about 1.5MPa and about 10 MPa, an ultimate compressive and tensile strength greater than about 1 MPa, an ultimate tensile stretch greater than about ~~[[25%]]~~ 15% in at least one direction, and comprises fabric extensions from the body for attachment to sides of a vertebrae.

30-33. (Canceled)

34. (Previously Presented) An implantable spinal disc body having a superior surface and an inferior surface joined by a circumferential surface comprised of a biocompatible

Attorney Docket No.: 9537-3
Application Serial No.: 10/658,932
Filed: September 9, 2003
Page 6 of 13

elastomer with a compressive modulus of elasticity less than about 100 megaPascals and an ultimate strength in tension greater than about 100 kiloPascals.

35. (Previously Presented) The implantable spinal disc body of claim 34 wherein the implantable spinal disc superior and inferior surfaces are substantially that of a kidney corresponding to a human spinal intervertebral disc shape, shaped and formed by an extended oval surface and an indented surface, and wherein the cross-section of the implantable spinal disc is substantially rectangular.

36. (Original) The implantable spinal disc body of claim 34, wherein the periphery of the superior and inferior surfaces is substantially flat.

37. (Original) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces have a roughness index of between about 1 nm and about 2 mm in height.

38. (Original) The implantable spinal disc body of claim 37, wherein the circumferential surface has a roughness index of less than 1 mm.

39. (Original) The implantable spinal disc body of claim 34, wherein the implantable spinal disc body is at least partially surrounded by an attachment extension member having a plurality of superior and inferior tabs connected to a band member for attachment of the implantable spinal disc to adjacent superior and inferior vertebral surfaces, respectively.

40. (Previously Presented) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces are covered with a surface treatment to promote attachment to adjacent vertebral bodies, and wherein the disc body is a plateless unitary body defined by a freeze-thaw hydrogel.

Attorney Docket No.: 9537-3
Application Serial No.: 10/658,932
Filed: September 9, 2003
Page 7 of 13

41. (Original) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces are provided with a plurality of pores to promote tissue ingrowth.

42. (Previously Presented) The implantable spinal disc body of claim 34 wherein an anterior portion of the implantable spinal disc body is of greater thickness than a posterior portion.

43. (Previously Presented) An implantable spinal disc body of a biocompatible elastomer material having a compressive modulus of elasticity that is less than about 100 megaPascals and an ultimate strength in tension greater than about 100 kiloPascals, the body comprising:

- a substantially concave superior surface having a substantially flat periphery surface;
- a substantially convex inferior surface having substantially flat periphery;
- the superior and inferior surfaces being joined by a circumferential surface; and
- the implantable spinal disc body being further characterized as being of a kidney shape formed by an extended oval surface and an indented portion, having a substantially rectangular cross-section, and having an anterior portion of greater thickness than a posterior portion.

44. (Original) The implantable spinal disc body of claim 43 wherein the superior and inferior surfaces have a roughness index of between about 1 nm and about 2 mm in height and the circumferential surface has a roughness index of less than 1 mm.

45. (Original) The implantable spinal disc body of claim 43 further comprising:

- an attachment extension band member at least partially surrounding the circumferential surface of the implantable spinal disc body; and
- a plurality of superior and inferior tabs extending from said attachment extension band member for attachment of the implantable spinal disc body to adjacent superior and inferior vertebral surfaces, respectively.

Attorney Docket No.: 9537-3
Application Serial No.: 10/658,932
Filed: September 9, 2003
Page 8 of 13

46. (Previously Presented) A prosthesis according to Claim 4, wherein the device is a plateless non-articulating unitary body.

47. (Previously Presented) The implantable spinal disc according to Claim 43, wherein the device has a non-articulating passively expandable unitary body of freeze-thaw cryogel that defines a core and annulus of the spinal disc implant.

48. (Previously Presented) An implantable spinal disc having a flexible unitary non-articulating solid body, the unitary body having a nucleus and annulus that are both defined by a crystalline PVA hydrogel, the unitary body having a shape generally similar to that of a human spinal intervertebral disc, wherein the crystalline PVA hydrogel has a compressive modulus of elasticity that is between about 1 MegaPascal to about 20 MegaPascals, and an ultimate tensile and compressive strength of at least about 100 kiloPascals.

49. (Previously Presented) A disc according to Claim 48, further comprising a mesh ring attached to an axially extending circumferential surface of the unitary body.

50. (Previously Presented) A disc according to Claim 48, wherein the mesh ring comprises a mesh fabric.

51. (Previously Presented) A disc according to Claim 48, further comprising a porous material attached to superior (top) and inferior (bottom) surfaces of the unitary body to allow for tissue ingrowth from adjacent vertebral tissue *in situ*.

52. (Previously Presented) A disc according to Claim 48, wherein the unitary body is configured to passively axially expand *in situ* by at least about 10% over time.

53. (Previously Presented) A disc according to Claim 48, wherein the unitary body is

Attorney Docket No.: 9537-3
Application Serial No.: 10/658,932
Filed: September 9, 2003
Page 9 of 13

configured to passively axially expand *in situ* between about 20% to about 40% over at least about 24 hours.

54. (Previously Presented) A disc according to Claim 53, wherein the unitary body is configured to expand in height *ex vivo* about 50% over about 24 hours when placed in a bath of Normal saline.

55. (Previously Presented) A disc according to Claim 48, wherein the unitary body has anisotropic elasticity.

56. (Previously Presented) A disc according to Claim 48, wherein the unitary body has substantially the same durometer for locations proximate the nucleus and the annulus.

57. (Previously Presented) A disc according to Claim 48, further comprising at least one inferior tab and at least one superior tab extending from the unitary body.

58. (Previously Presented) A disc according to Claim 52, further comprising a polyester fabric attached to the upper and lower surfaces of the unitary body.

59. (Previously Presented) A disc according to Claim 48, wherein the crystalline PVA hydrogel is devoid of structural reinforcement and is defined by a freeze-thaw PVA hydrogel.

60. (Currently Amended) A disc according to Claim 48, wherein the unitary body has a compressive modulus of elasticity of at least about $[[10]] \geq$ MPa, and an ultimate strength in tension and compression of a least about 1 MPa to thereby provide a relatively compliant body that has sufficient elasticity to allow flexible motion between vertebrae and act as a mechanical shock absorber.

Attorney Docket No.: 9537-3
Application Serial No.: 10/658,932
Filed: September 9, 2003
Page 10 of 13

61. (Previously Presented) A disc according to Claim 60, wherein the unitary body has a mechanical ultimate strength in compression of at least about 10 MPa.

62. (Previously Presented) A disc according to Claim 48, wherein the unitary body has opposing top and bottom faces, and wherein the unitary body can withstand between about 2-10 degrees of rotation between the top and bottom faces with torsions of between about 0.1 N-m to about 1 N-m.

63. (Previously Presented) A spinal disc prosthesis having a solid unitary body consisting essentially of a non-reinforced freeze-thaw PVA cryogel that defines a core and annulus, wherein the body has a compressive modulus of elasticity that is less than 100 MegaPascals and greater than about 0.1 MegaPascals, and an ultimate tensile strength that is greater than about 100 kiloPascals.

64. (Previously Presented) A spinal disc prosthesis according to Claim 63, wherein the unitary body has compressive modulus of elasticity that is between about 0.1 MegaPascal to about 10 MegaPascals.

65. (Previously Presented) A spinal disc prosthesis according to Claim 64, wherein the unitary body has an ultimate stretch in at least one direction of at least about 15%.

66. (Previously Presented) A spinal disc prosthesis according to Claim 63, wherein the body is unbounded on upper and lower surfaces to allow for axial expansion of about 20% when placed in a Normal saline solution for about 24 hours.

Attorney Docket No.: 9537-3
Application Serial No.: 10/658,932
Filed: September 9, 2003
Page 11 of 13

67. (Previously Presented) A spinal disc prosthesis according to Claim 63, wherein the unitary body has opposing top and bottom faces, and wherein the unitary body can withstand at least about 2 degrees of rotation between the top and bottom faces with torsions of at least about 0.1 N-m without failing.

68. (Previously Presented) A spinal disc prosthesis according to Claim 67, wherein the unitary body can withstand between about 2 degrees to at least about 10 degrees of rotation between the top and bottom faces with torsions between about 0.1 N-m to about 1 N-m without failing.

69. (Previously Presented) A spinal disc prosthesis according to Claim 63, further comprising a non-metallic mesh sleeve on an axially extending surface thereof.

70. (Previously Presented) A spinal disc prosthesis according to Claim 63, wherein the unitary body has anisotropic elasticity.

71. (Previously Presented) A spinal disc prosthesis according to Claim 63, further comprising a plurality of axially extending tabs of that are attached to the unitary body and extend beyond upper and lower bounds of the unitary body in the axial direction.

72. (New) A spinal disc prosthesis according to Claim 63, further comprising a mesh material disposed on at least one surface of the solid body.

73. (New) A spinal disc prosthesis according to Claim 72, wherein, in position, the mesh material is affixed to vertebral bone.